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| 09/991,381 | 10/22/2001 | William M. Adams | 00013/01UTL | 2660 |

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| EXAMINER | |
|---|---|
| KOPPIKAR, VIVEK D | |
| ART UNIT | PAPER NUMBER |
| 3626 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/19/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/991,381 | ADAMS, WILLIAM M. | |
| | Examiner | Art Unit | |
| | Vivek D. Koppikar | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

1. Claims 1-38 have been examined in this application. This is the first office action since the applicants filed a Request for Continued Examination (RCE) on January 31, 2007.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 4-12, 14-22, 24-27, 29-34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,496,804 to McEvoy in view of US Patent Application Publication 2005/0033639 to Myers and in further view of US Patent Number 5,832,449 to Cunningham (from the applicant's Information Disclosure Statement (IDS)).

(A) As per claim 1, a method for distributing pharmaceutical (product) drug samples, comprising the step of adjudicating a claim by a drug dispenser at a claim adjudication system for pharmacy benefit claims (McEvoy: Col. 2, Ln. 51-58 and Col. 4, Ln. 61-Col. 5, Ln. 5).

McEvoy does not teach that the product (pharmaceutical) is obtained by a token being distributed by a prescriber to permit the patient to obtain the pharmaceutical drug sample from the drug dispenser, however, this feature is well known in the art as evidenced by Myers (Section [0125]). At the time of the invention, it would have been obvious for one skilled in the art to have modified the method of McEvoy with the aforementioned teachings from Myers with the motivation of having a means of receiving a discount on a product (including a 100% discount) ,

as recited in Myers (Sections [0007] and [0008]). (Note: The method of McEvoy relates to any product (Col. 1, 12-20) which the examiner interprets to encompass a pharmaceutical product or a drug sample. In the method of McEvoy the redemption by the customer takes place when a customer presents a coupon, however, as taught in Myers this redemption of the product could also take place by the presentation of a token by a customer. The Examiner interprets the term "token" broadly to include an object which is used to represent something, including a coupon or voucher which represents a discount (Myers: Sections [0007] and [0008]).

In the combined teachings of McEvoy in view of Myers the adjudication system for pharmacy benefits claims is not electronic, however, Cunningham teaches an electronic processing system to process a pharmacy benefits claim (Cunningham: Col. 12, Ln. 8-11). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of McEvoy in view of Myers and Cunningham with the aforementioned from Cunningham with the motivation of providing an enhanced compensation means for pharmacies which are dispensing pharmaceutical products to patients and for providing a means for recording transactions surrounding the prescription and distribution of pharmaceutical trial products on a computer, as recited in Cunningham (Col. 3, Ln. 49-54 and Col. 12, Ln. 8-11).

(B) As per claim 2, in the combined method of McEvoy in view of Myers and Cunningham and Cunningham the step of adjudicating comprises steps of:

receiving at the claim adjudication system a request for adjudication in a first predefined format from the drug dispenser (McEvoy: Col. 4, Ln. 61-Col. 5, Ln. 5); and

sending to the drug dispenser an adjudication response (over a communications network)in the predefined format in response to the request for adjudication (McEvoy: Col. 4, Ln. 61-Col. 5, Ln. 15).

McEvoy does not explicitly teach that the step of receiving the request for a claim adjudication from a pharmacy and the step of sending to the pharmacy (drug dispenser) an adjudication response (e.g. payment) takes place electronically, however, Cunningham teaches that a pharmacy is communicatively linked with a central computing station that manages pharmaceutical product trials (Cunningham: Col. 4, Ln. 34-64). Cunningham further discloses the step of performing an audit and accounting function (of the pharmacy) and compensating (reimbursing) the pharmacy for the actual (amount) of pharmaceutical product dispensing (Cunningham: Col. 12, Ln. 8-11). Therefore, the examiner takes the position that the step of receiving at the claim adjudication system a request for adjudication in a first predefined format (e.g. electronic format) from the drug dispenser is within the scope of feature in Cunningham wherein the pharmacy and the central computing station communicate with each other (via a communicative link). The motivation from Cunningham for making this modification to the combined teachings of McEvoy in view of Myers and Cunningham is the same as that set forth in the rejection of claim 1, above.

(C) As per claim 4, in the combined method of McEvoy in view of Myers and Cunningham the steps of receiving and sending are performed using a communications network for communications between a plurality of drug dispensers and a plurality of adjudicators for the electronic processing of pharmacy benefit claims (McEvoy: Col. 4, Ln. 61-Col. 5, Ln. 15 and Cunningham: Col. 4, Ln. 34-64 and Col. 12, Ln. 8-11). The motivation from Cunningham for

making this modification to the combined teachings of McEvoy in view of Myers and Cunningham is the same as that set forth in the rejection of claim 1, above.

(D) As per claim 5, in the method of McEvoy in view of Myers and Cunningham the step of adjudicating further comprises the steps of:

receiving information about tokens that are distributed (McEvoy: Col. 5, Ln. 15-57);

receiving information about the token from the drug dispenser (McEvoy: Col. 5, Ln. 15-57); and

processing the request to provide the adjudication response using the information about tokens that were distributed, the information about the tokens from the drug dispenser, and business logic related to the token (McEvoy: Col. 5, Ln. 15-57).

(E) As per claim 6, in the method of McEvoy in view of Myers and Cunningham the step of adjudicating further comprises a step of receiving information about the prescribers to which tokens were distributed, wherein the information about the token received from the drug dispenser comprises prescriber information, and the step of processing further comprises a step of comparing the information about the prescriber with the information about the prescriber to which tokens are distributed (McEvoy: Col. 5, Ln. 15-57).

(F) As per claim 7, in the method of McEvoy in view of Myers and Cunningham the step of adjudicating further comprises steps of storing token usage data related to the token, and periodically providing the token usage data to enable evaluation of a pharmaceutical drug sample distribution program (McEvoy: Col. 5, Ln. 15-57).

(G) As per claim 8, in the method of McEvoy in view of Myers and Cunningham the step of adjudicating further comprises a step of providing formulary management services and drug

utilization review services (Cunningham: Col. 3, Ln. 14-16). The motivation from Cunningham for making this modification to the combined teachings of McEvoy in view of Myers and Cunningham is the same as that set forth in the rejection of claim 1, above.

(H) As per claim 9, the method of McEvoy in view of Myers and Cunningham includes a step of entering information related to the token into a pharmacy benefit management system used for dispensing pharmaceutical drugs and for sending and receiving adjudication communications (McEvoy: Col. 4, Ln. 61-Col. 5, Ln. 5).

(I) As per claim 10, the method of McEvoy in view of Myers and Cunningham further comprising a step of distributing tokens for delivery to prescribers (Myers: Col. 2, Ln. 13-30).

(J) As per claim 11, the method of McEvoy in view of Myers and Cunningham teaches a step of storing token distribution data related to the tokens, the token distribution data including prescriber information to identity prescribers to whom the tokens were distributed (McEvoy: Col. 5, Ln. 15-57).

(K) As per claim 12, in the method of McEvoy in view of Myers and Cunningham further comprising steps of:

periodically receiving token usage data related to the token, the token usage data being generated and stored by the claim adjudication system (McEvoy: Col. 5, Ln. 15-57); and

correlating the token usage data with token distribution data (McEvoy: Col. 5, Ln. 15-57).

(L) As per claim 14, the method of McEvoy in view of Myers and Cunningham teaches a step of accounting to the drug dispenser for the dispensing of the pharmaceutical drug sample (McEvoy: Col. 5, Ln. 15-57).

(M) As per claims 15-21, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

(N) As per claims 22, 24-26, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

(O) As per claims 27, 29-33, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

(P) As per claims 34-36, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

(Q) As per claims 37-38, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over McEvoy in view of Myers and Cunningham as applied to Claim 2, above, and in further view of US Patent Number 5,666,490 to Gillings.

(A) As per claim 3, the combined method of McEvoy in view of Myers and Cunningham does not teach that the step of receiving and sending are performed in accordance with a protocol for electronic processing of pharmacy benefit claims, however, this feature is well known in the art as evidenced by Gillings (Claim 1, part (k)). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined method of McEvoy in view of Myers and Cunningham with the aforementioned feature from Gillings with the motivation of improving the quality and integrity of the process of managing pharmaceutical data, as recited in Gillings (Col. 1, Ln. 65-Col. 2, Ln. 3).

(B) As per claims 23, 28 and 35, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over McEvoy in view of Myers and Cunningham, as applied to Claim 1, above.

(A) The combined method of McEvoy in view of Myers and Cunningham does not teach a step of prescribing the pharmaceutical drug sample for a patient using the token, however, the examiner takes Official notice that this practice is well-known in health care field. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the method of McEvoy in view of Myers and Cunningham by implementing the aforementioned practice with the motivation of providing a means allowing doctors (prescribers) to regulate the dispensing of prescription drugs.

***Response to Arguments***

6. Applicant's arguments filed on January 31, 2007 with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

***Examiner's Suggestions***

7. The Examiner recommends amending the claims to recite a step wherein it is necessary for patients to attend or visit a doctor or prescriber in order to receive a prescription, in which the prescription is represented by a token for a pharmaceutical drug sample. The Examiner also recommends recited features such as "customized tokens" (for patients) since virtually all prescriptions are customized to meet the needs of a particular patient. Any amendment to the claims , however, must have support in the specification as originally filed. In addition, any amendment to the claim will be subject to an updated prior art search.

*Conclusion*

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either

Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

3/26/2007

Carolyn Bleck
Patent Examiner - 3626
4/16/07